IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.p.A. and ANGELINI PHARMA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
INTELLIPHARMACEUTICS INTERNATIONAL, INC., INTELLIPHARMACEUTICS CORPORATION, AND INTELLIPHARMACEUTICS LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A ("A.C.R.A.F.") and Angelini Pharma, Inc. ("API") (collectively, "Angelini" or "Plaintiffs") allege for their complaint against Intellipharmaceutics International, Inc., Intellipharmaceutics Corporation, and Intellipharmaceutics Ltd. (collectively, "Intellipharmaceutics" or "Defendants") as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,133,893 ("the '893 Patent") under 35 U.S.C. §271(e)(2) and declaration of infringement of that same patent.

THE PARTIES

2. Plaintiff A.C.R.A.F. is a corporation organized under the laws of Italy having a place of business at Viale Amelia, 70, Rome Italy 00181.

3. Plaintiff API is a limited liability company organized under the laws of Delaware having a place of business at 8322 Helgerman Court, Gaithersburg, Maryland 20877.

4. On information and belief, Intellipharmaceutics International, Inc. ("IPC

International") is a Canadian corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC International is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On information and belief, IPC International owns, directly or through its wholly owned subsidiary Intellipharmaceutics Ltd. ("IPC Ltd."), 100.00% of the common shares of Intellipharmaceutics Corporation ("IPC Corp."). On information and belief, IPC International has previously submitted to this Court's jurisdiction.

5. On information and belief, IPC Corp, is a Canadian corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC International is the ultimate parent of IPC Corp. On information and belief, IPC Corp. is the operating affiliate of IPC Ltd. On information and belief, IPC Corp., with the assistance and/or direction of IPC International and/or IPC Ltd. develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use in the State of Delaware and throughout the United States. On information and belief, IPC Corp. has previously submitted to this Court's jurisdiction. IPC Corp. has purposefully availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

6. On information and belief, IPC Ltd., is a Delaware Corporation having a principal pace of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC Ltd. is a wholly owned subsidiary of IPC International. On information and belief, IPC Ltd., with the assistance and/or direction of IPC International and/or IPC Corp. develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use in the state of Delaware and throughout the United States. On information and belief, IPC Ltd.

has previously submitted to this Court's jurisdiction. IPC Ltd. has purposefully availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

7. On information and belief, IPC Ltd., IPC Corp., and IPC International have common officers and directors and have represented to the public that they are a unitary entity.

JURISDICTION AND VENUE

8. This action arises under 35 U.S.C. Section 1, *et seq.* and 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over IPC by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Delaware.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

11. The '893 Patent, entitled "Trazodone and trazodone hydrochloride in purified form," issued on March 13, 2012. A copy of the '893 Patent is attached to this complaint as Exhibit A.

12. A.C.R.A.F. owns the entire right and interest in the '893 Patent.

13. API is the owner of U.S. Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 022411 for a extended release formulation of trazodone hydrochloride, marketed and sold in the United States under the brand name, OLEPTRO®, and

has exclusive rights to make, use, sell, and offer for sale trazodone hydrochloride under the '893 Patent for purposes of NDA No. 022411.

14. In conjunction with NDA No. 022411, API has listed the '893 Patent and other patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") maintained by the U.S. Food and Drug and Administration. Listing patents in the Orange Book obligates drug companies seeking approval to market a generic version of a listed drug (*e.g.*, OLEPTRO®) before the expiration of a listed patent to provide notice to the owner of the listed patent(s) and to the NDA holder with certain exceptions which do not apply to this case.

15. Upon information and belief, Defendants, either directly or indirectly, submitted ANDA No. 205-400 to the FDA for approval to market trazodone hydrochloride extended release oral tablets, dosage forms 150 mg and 300 mg, covered by NDA No. 022411.

16. Upon information and belief, ANDA No. 205-400 refers to, and relies upon, API's NDA No. 022411 and contains data that, according to Defendants, demonstrates the bioequivalence of the Defendants' proposed ANDA product to API's OLEPTRO® which is the subject of NDA No. 022411.

17. Upon information and belief, Defendants submitted ANDA No. 205-400 to the FDA seeking approval for the commercial manufacture, marketing and sale of the trazodone hydrochloride extended release oral tablets, dosage forms 150 mg and 300 mg, in the event that the FDA approves that ANDA.

18. In an undated letter received by counsel for Angelini on August, 13, 2014, Defendants advised A.C.R.A.F. and API that it had filed ANDA No. 205-400, seeking approval

to market a generic version of OLEPTRO®. This proceeding is being filed within 45 days of receipt of the undated letter by counsel for Angelini pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

19. The undated letter advises Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 that ANDA No. 205-400 was purportedly filed with a Paragraph IV certification to obtain approval to market trazodone hydrochloride extended release oral tablets, dosage forms 150 mg and 300 mg, before the expiration of, *inter alia*, the '893 Patent.

20. Upon information and belief, Defendants admit that the trazodone hydrochloride used to formulate Defendants' ANDA products meets the purity limitation of at least claim 1 of the '893 Patent.

21. The claims of the '893 Patent have a statutory presumption of validity that exists at all stages of a proceeding.

22. Defendants' detailed notice accompanying its undated letter to Plaintiffs demonstrates that Defendants have actual knowledge of the '893 Patent and that its ANDA product infringes at least claims 1, 2 and 5-8 of the '893 Patent.

23. Plaintiffs reserve the right to amend the complaint to add and/or substitute a different party for Defendants if, through discovery, Plaintiffs discover that a company other than Defendants are or will be formulating, using, selling, offering to sell, manufacturing, and/or importing the trazodone hydrochloride extended release oral tablets that are the subject of ANDA No. 205-400 within the United States, or the trazodone hydrochloride used to formulate the product that is the subject of ANDA No. 205-400.

COUNT 1
Infringement of the '893 Patent Under 35 U.S.C. § 271(e)(2)

24. Paragraphs 1-23 are incorporated herein as set forth above.

25. Defendants' submission, directly or indirectly, of ANDA No. 205-400 to obtain

FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of trazodone hydrochloride extended release oral tablets in the United States before the expiration of the '893 Patent was an act of infringement of the '893 Patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, Defendants were aware of the existence of the '893 Patent and were aware that the filing of ANDA No. 205-400 and certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '893 Patent constituted infringement of that patent. This is an exceptional case.

COUNT 2

Declaratory Judgment of Infringement of the '893 Patent under 35 U.S.C. § 271

27. Paragraphs 1-26 are incorporated herein as set forth above.

28. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(a), (b) and (c).

29. There is a concrete and immediate dispute between Plaintiffs and Defendants that create an actual case or controversy permitting the court to entertain Plaintiffs' request for declaratory relief pursuant to Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this court.

30. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or use within the United States, and/or import into the United States the Defendants' trazodone hydrochloride extended release oral tablets which are the subject of ANDA No. 205-400 prior to expiry of the '893 Patent.

31. Defendants' actions, including, but not limited to, the submission of ANDA No. 205-400 indicate a refusal to change the course of their action.

32. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of the trazodone hydrochloride extended release oral tablets which are the subject of ANDA No. 205-400 prior to expiration of the '893 Patent will infringe the '893 Patent.

33. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially import, manufacture, use, offer for sale or sell Defendants' trazodone hydrochloride extended release oral tablets which are the subject of ANDA No. 205-400 within the United States, or induce or contribute to such conduct, Defendants will infringe the '893 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed the '893 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 205-400 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale or sale within the United States and/or importation into the United States of the Defendants' trazodone hydrochloride extended release oral tablets which are the subject of ANDA No. 205-400, prior to the expiry of the '893 Patent, will infringe the '893 Patent;

B. A declaration pursuant to 35 U.S.C. § 2201 that Defendants' proposed commercial manufacture, use, offer for sale and/or sale of Defendants' trazodone hydrochloride extended release oral tablets which are the subject of ANDA No. 205-400 within the United States and/or its commercial importation into the United States, prior to the expiry of the '893 Patent, will infringe the '893 Patent;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 205-400 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration date of the '893 Patent or any extension thereof;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, servants, employees, licensees and representatives, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '893 Patent for the full term thereof;

E. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the court may deem just and proper.

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